



Dkt. 59331-E/JPW/MAF/AJD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: James M. Binley et al.
U.S. Serial No.: 10/780,993
Filed: February 18, 2004
For: STABILIZED VIRAL ENVELOPE PROTEINS AND USES
THEREOF

1185 Avenue of the Americas
New York, New York 10036
March 26, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the PTO-1449 form attached hereto as **Exhibit A**. A copy of reference 3 is attached as **Exhibit 1**.

1. U.S. Patent No. 5,886,163, issued to K.W. Hasel and P.J. Maddon on March 23, 1999;
2. U.S. Patent No. 5,935,579, issued to J.A. Habeshaw et al. on August 10, 1999;
3. Allowed claims in J.M. Binley et al., U.S. Serial No. 09/602,864, filed June 23, 2000 (**Exhibit 1**);
4. Atwell, S. et al. (1997) Stable Heterodimers from Remodeling the Domain Interface of a Homodimer using a Phage Display Library, J. Mol. Biol. 270: 26-35;

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Page 2

5. Barouch, D.H. and N.L. Letvin (2000) DNA Vaccination for HIV-1 and SIV, Intervirology 4: 282-287;
6. Barouch, D.H. et al. (2002) Eventual AIDS Vaccine Failure in a Rhesus Monkey by Viral Escape from Cytotoxic T Lymphocytes, Nature 415: 335-339;
7. Binley, J. et al. (2000) A Recombinant Human Immunodeficiency Virus Type 1 Envelope Glycoprotein Complex Stabilized by an Intermolecular Disulfide Bond Between the GP 120 and GP 41 Subunits is an Antigenic Mimic of the Trimeric Viron-Associated Structure, J. Virol. 74: 627-643;
8. Burton, D.R. et al. (1994) Efficient Neutralization of Primary Isolates of HIV-1 by a Recombinant Human Monoclonal Antibody. Science 266: 1024-1027;
9. Burton, D.R. and J.P. Moore (1998) Why do we Not Have an HIV Vaccine and how Can we Make One? Nature Med. Vaccine Suppl. 4(5): 495-498;
10. Cao, J. et al. (1997) Replication and Neutralization of Human Immunodeficiency Virus Type 1 Lacking the V1 and V2 Variable Loops of the gp120 Envelope Glycoprotein, J. Virol. 71: 9808-9812;
11. Edinger, A.L. et al. (1999) Functional Dissection of CCR5 Coreceptor Function through the Use of CD4-Independent Simian Immunodeficiency Virus Strains, J. Virol. 73: 4062-4073;

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Page 3

12. Farzan, M. et al. (1998) Stabilization of Human Immunodeficiency Virus Type 1 Envelope Glycoprotein Trimers by Disulfide Bonds Introduced into the GP 41 Glycoprotein Ectodomain, J. Virol. 72: 7620-7625;
13. Fouts, T.R. et al. (1998) Interactions of Polyclonal and Monoclonal Anti-Glycoprotein 120 Antibodies with Oligomeric Glycoprotein 120-Glycoprotein 41 Complexes of a Primary HIV Type 1 Isolate: Relationship to Neutralization, AIDS Res. Human Retrovir. 14: 591-597;
14. Fouts, T.R. et al. (1997) Neutralization of the Human Immunodeficiency Virus Type 1 Primary Isolate JR-FL by Human Monoclonal Antibodies Correlates with Antibody Binding to the Oligomeric Form of the Envelope glycoprotein Complex, J. Virol. 71: 2779-2785;
15. Gallaher, W.R. et al. (1995) A General Model for the Surface Glycoproteins of HIV and Other Retroviruses, AIDS Res. Human Retrovir. 11: 191-202;
16. Haynes, B.F. (1996) HIV Vaccines: Where are we and Where are we Going? Lancet 348: 933-937;
17. Helseth, E. et al. (1991) Human Immunodeficiency Virus Type 1 gp120 envelope Glycoprotein Regions Important for Association with the gp41 Transmembrane Glycoprotein, J. Virol. 65(4): 2119-2123;
18. Johnston, M.I. and J. Flores (2001) Progress in HIV Vaccine Development, Curr. Opin. Pharmacol. 1(5): 504-510;

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19. Joy, A.K. et al. (1999) Can HIV Infection be Prevented with a Vaccine? *Drugs R&D* 6: 431-440;
20. Labranche, C.C. et al. (1994) Biological, Molecular, and Structural Analysis of a Cytopathic Variant from a Molecularly Cloned Simian Immunodeficiency Virus. *J. Virol.* 68: 5509-5522;
21. Labranche, C.C. et al. (1994) Biological, Molecular, and Structural Analysis of a Cytopathic Variant from a Molecularly Cloned Simian Immunodeficiency Virus. *J. Virol.* 68: 7665-7667;
22. Maerz, A.L. et al. (2001) Functional Analysis of the Disulfide-Bonded Loop/Chain Reversal Region of Human Immunodeficiency Virus Type 1 gp41 reveals a Critical Role in gp120-gp41 Association, *J. Virol.* 75(14): 6635-6644;
23. McInerney, T.L. et al. (1998) Mutation-Directed Chemical Cross-Linking of Human Immunodeficiency Virus Type 1 gp41 Oligomers, *J. Virol.* 72: 1523-1533;
24. Mitchell, W.M. et al. (1998) Inactivation of a Common Epitope Responsible for the Induction of Antibody-Dependent Enhancement of HIV, *AIDS* 12: 147-156;
25. Moore, J.P. et al. (1994a) "Probing the Structure of the Human Immunodeficiency Virus Surface Glycoprotein gp120 with a Panel of Monoclonal Antibodies, *J. Virol.* 68: 469-484;

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26. Moore, J.P. et al. (1994b) Immunological Evidence for Interactions between the First, Second, and Fifth Conserved Domains to the gp120 Surface Glycoprotein of Human Immunodeficiency Virus Type 1, J. Virol. 68(11): 6836-6847;
27. Murphy, F.A. (1996) "Virus Taxonomy," in Fields Virology, Third Edition, B.N. Fields, et al. eds., Lippincott-Raven Publisher, Philadelphia, pp. 40 and 41;
28. Parren, P.W. et al. (1997) HIV-1 Antibody - Debris or Virion? Nat. Med. 3: 366-367;
29. Parren, P.W. et al. (1998) Neutralization of Human Immunodeficiency Virus Type 1 by Antibody to gp120 is Determined Primarily by Occupancy of Sites on the Virion Irrespective of Epitope Specificity, J. Virol. 72: 3512-3519;
30. Reitter, J.N. et al. (1998) A Role for Carbohydrates in Immune Evasion in AIDS, Nat. Med. 4: 679-684;
31. Schulz, T.F. et al. (1992) Conserved Structural Features in the Interaction between Retroviral Surface and Transmembrane Glycoproteins? AIDS Res. Hum. Retrovirus 8(9): 1571-1580;
32. Stamatatos, L. et al. (1994) Differential Regulation of Cellular Tropism and Sensitivity to Soluble CD4 Neutralization by the Envelope gp120 of Human Immunodeficiency Virus Type 1, J. Virol. 68: 4973-4979;
and

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33. Trkola, A. et al. (1996) Human Monoclonal Antibody 2G12 Defines a Distinctive Neutralization Epitope on the gp120 Glycoprotein of Human Immunodeficiency Virus Type 1. J. Virol. 70: 1100-1108.

The subject application is a continuation application of U.S. Serial No. 09/602,864, filed June 23, 2000, which in turn is a continuation-in-part of, and claims the priority date of, U.S. Provisional Application No. 60/141,168, filed June 25, 1999. Except for reference 3, all of the above-listed references have previously been submitted to, or cited by, the U.S. Patent and Trademark Office in connection with U.S. Serial No. 09/602,864, an application relied upon by the present application for an earlier effective filing date. Specifically, references 4, 10, 11, 13-15, 25 and 28-31 were submitted to the Patent Office in an Information Disclosure Statement filed September 13, 2000. References 2, 23, 24 and 32 were submitted to the Patent Office in a Supplemental Information Disclosure Statement filed November 30, 2000. References 7 and 12 were submitted to the Patent Office in a Supplemental Information Disclosure Statement filed April 23, 2003. References 1, 8, 20, 21 and 33 were submitted to the Patent Office in a Supplemental Information Disclosure Statement filed July 9, 2003. References 5, 6, 9, 16-19, 22, 26 and 27 were cited by the U.S. Patent and Trademark Office in an Office Action issued on March 1, 2002. Accordingly, pursuant to 37 C.F.R. §1.98(d), copies of these references are not provided herein since they were previously submitted to, or cited by, the Patent Office in an application relied upon for an earlier effective filing date under 35 U.S.C. §120.

Applicants note that the above-cited reference 3 refers to a patent application containing the identical disclosure as the

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present application, and which has neither been issued as a patent nor published. Pursuant to 37 C.F.R. §1.98(c), a copy of U.S. Serial No. 09/602,864 cited in reference 3 is not provided herein as it is cumulative. However, pursuant to 37 C.F.R. §1.98(a)(2), a copy of the claims allowed in this application is attached hereto as **Exhibit 1**.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone at the number provided below.

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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VA 22313-1450

Mark A. Farley 3-26-04
John P. White Date
Reg. No. 28,678
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Reg. No. 33,170



Form PTO-1449

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Patent and Trademark Office

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INFORMATION DISCLOSURE CITATION
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Group Art Unit

U.S. PATENT DOCUMENTS

Examiner Initials	Exh. No.	Document Number							Date	Name	Class	Subclass	Filing Date If Appropriate
		5	8	8	6	1	6	3	03/23/99	Binley et al.			
		5	9	3	5	5	7	9	08/10/99	Habeshaw et al.			
	1	Allowed claims in U.S. Serial No. 09/602,864								Binley et al.			06/23/00

FOREIGN PATENT DOCUMENTS

		Document Number							Date	Country	Class	Subclass	Translation	
													Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Atwell, S. et al. (1997) Stable Heterodimers from Remodeling the Domain Interface of a Homodimer using a Phage Display Library, J. Mol. Biol. 270: 26-35;
	Barouch, D.H. and N.L. Letvin (2000) DNA Vaccination for HIV-1 and SIV, Interviro. 4: 282-287;
	Barouch, D.H. et al. (2002) Eventual AIDS Vaccine Failure in a Rhesus Monkey by Viral Escape from Cytotoxic T Lymphocytes, Nature 415: 335-339;
	Binley, J. et al. (2000) A Recombinant Human Immunodeficiency Virus Type 1 Envelope Glycoprotein Complex Stabilized by an Intermolecular Disulfide Bond Between the GP 120 and GP 41 Subunits is an Antigenic Mimic of the Trimeric Viron-Associated Structure, J. Virol. 74: 627-643;
	Burton, D.R. et al. (1994) Efficient Neutralization of Primary Isolates of HIV-1 by a Recombinant Human Monoclonal Antibody. Science 266: 1024-1027;
	Burton, D.R. and J.P. Moore (1998) Why do we Not Have an HIV Vaccine and how Can we Make One? Nature Med. Vaccine Suppl. 4(5): 495-498;
	Cao, J. et al. (1997) Replication and Neutralization of Human Immunodeficiency Virus Type 1 Lacking the V1 and V2 Variable Loops of the gp120 Envelope Glycoprotein, J. Virol. 71: 9808-9812;

EXAMINER
DATE CONSIDERED

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		Edinger, A.L. et al. (1999) Functional Dissection of CCR5 Coreceptor Function through the Use of CD4-Independent Simian Immunodeficiency Virus Strains, J. Virol. 73: 4062-4073;	
		Farzan, M. et al. (1998) Stabilization of Human Immunodeficiency Virus Type 1 Envelope Glycoprotein Trimers by Disulfide Bonds Introduced into the GP 41 Glycoprotein Ectodomain, J. Virol. 72: 7620-7625;	
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		Fouts, T.R. et al. (1997) Neutralization of the Human Immunodeficiency Virus Type 1 Primary Isolate JR-FL by Human Monoclonal Antibodies Correlates with Antibody Binding to the Oligomeric Form of the Envelope glycoprotein Complex, J. Virol. 71: 2779-2785;	
		Gallaher, W.R. et al. (1995) A General Model for the Surface Glycoproteins of HIV and Other Retroviruses, AIDS Res. Human Retrovir. 11: 191-202;	
		Haynes, B.F. (1996) HIV Vaccines: Where are we and Where are we Going? Lancet 348: 933-937;	
		Helseth, E. et al. (1991) Human Immunodeficiency Virus Type 1 gp120 envelope Glycoprotein Regions Important for Association with the gp41 Transmembrane Glycoprotein, J. Virol. 65(4): 2119-2123;	
		Johnston, M.I. and J. Flores (2001) Progress in HIV Vaccine Development, Curr. Opin. Pharmacol. 1(5): 504-510;	
		Joy, A.K. et al. (1999) Can HIV Infection be Prevented with a Vaccine? Drugs R&D 6: 431-440;	
		Labranche, C.C. et al. (1994) Biological, Molecular, and Structural Analysis of a Cytopathic Variant from a Molecularly Cloned Simian Immunodeficiency Virus. J. Virol. 68: 5509-5522;	
		Labranche, C.C. et al. (1994) Biological, Molecular, and Structural Analysis of a Cytopathic Variant from a Molecularly Cloned Simian Immunodeficiency Virus. J. Virol. 68: 7665-7667;	
		Maerz, A.L. et al. (2001) Functional Analysis of the Disulfide-Bonded Loop/Chain Reversal Region of Human Immunodeficiency Virus Type 1 gp41 reveals a Critical Role in gp120-gp41 Association, J. Virol. 75(14): 6635-6644;	
		McInerney, T.L. et al. (1998) Mutation-Directed Chemical Cross-Linking of Human Immunodeficiency Virus Type 1 gp41 Oligomers, J. Virol. 72: 1523-1533;	
		Mitchell, W.M. et al. (1998) Inactivation of a Common Epitope Responsible for the Induction of Antibody-Dependent Enhancement of HIV, AIDS 12: 147-156;	
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		Moore, J.P. et al. (1994a) "Probing the Structure of the Human Immunodeficiency Virus Surface Glycoprotein gp120 with a Panel of Monoclonal Antibodies, J. Virol. 68: 469-484;		
		Moore, J.P. et al. (1994b) Immunological Evidence for Interactions between the First, Second, and Fifth Conserved Domains to the gp120 Surface Glycoprotein of Human Immunodeficiency Virus Type 1, J. Virol. 68(11): 6836-6847;		
		Murphy, F.A. (1996) "Virus Taxonomy," in Fields Virology, Third Edition, B.N. Fields, et al. eds., Lippincott-Raven Publisher, Philadelphia, pp. 40 and 41;		
		Parren, P.W. et al. (1997) HIV-1 Antibody - Debris or Virion? Nat. Med. 3: 366-367;		
		Parren, P.W. et al. (1998) Neutralization of Human Immunodeficiency Virus Type 1 by Antibody to gp120 is Determined Primarily by Occupancy of Sites on the Virion Irrespective of Epitope Specificity," J. Virol. 72: 3512-3519;		
		Reitter, J.N. et al. (1998) A Role for Carbohydrates in Immune Evasion in AIDS, Nat. Med. 4: 679-684;		
		Schulz, T.F. et al. (1992) Conserved Structural Features in the Interaction between Retroviral Surface and Transmembrane Glycoproteins? AIDS Res. Hum. Retrovirus 8(9): 1571-1580;		
		Stamatatos, L. et al. (1994) Differential Regulation of Cellular Tropism and Sensitivity to Soluble CD4 Neutralization by the Envelope gp120 of Human Immunodeficiency Virus Type 1, J. Virol. 68: 4973-4979; and		
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